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Press Office

Press release

Merck KGaA withdraws its application for an extension of the indication for Erbitux (cetuximab)

The European Medicines Agency has been formally notified by Merck KGaA of its decision to withdraw its application for an extension of the therapeutic indication for the centrally authorised medicine Erbitux (cetuximab), 5 mg/mL solution for infusion.

On 18 March 2011, Merck KGaA submitted an application to extend the marketing authorisation for Erbitux to the treatment of non-small-cell lung cancer (NSCLC). At the time of the withdrawal, the application was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

Erbitux was first authorised in the European Union on 29 June 2004 and it is currently indicated for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, KRAS wild-type metastatic colorectal cancer. It is also indicated for the treatment of patients with squamous cell cancer of the head and neck.

In its official letter, the company stated that it decided to withdraw the application because the data currently available suggest that further data will be required to overcome the uncertainties raised by the CHMP.

Erbitux continues to be authorised in the currently approved indications.

More information about Erbitux and the state of the scientific assessment at the time of the withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the Agency's website after the 17-20 September 2012 CHMP meeting.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. More information on the work of the European Medicines Agency can be found on its website:
www.ema.europa.eu

Contact our press officers

Monika Benstetter or Martin Harvey Allchurch

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu